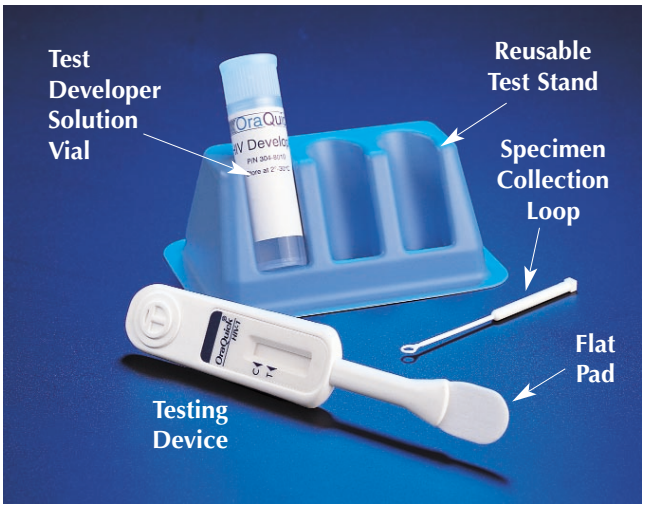
OraQuick®
Rapid HIV-1 Antibody Test

Step-by-Step Instructions for OraQuick® Rapid HIV-1 Antibody Test



Materials Supplied:

The OraQuick® Rapid HIV-1 Antibody Test consists of:

- A single-use testing device,
- A single-use test developer solution vial,
- A reusable test stand, and
- Disposable single-use specimen collection loops.

In addition, you will need to have a timer or watch, for timing the 20 to 60 minute test development time.

Other items that may be needed:

- Standard materials for collection of blood from the finger (e.g., lancet, antiseptic wipe, sterile gauze pad).

Please note:

Handle all specimens and materials contacting specimens as infectious waste.[1]

[1] See "Universal Precautions," CDC, MMWR, June 24, 1988.

For Investigational Use Only
The perfomance characteristics of this product have not been established.

GENERAL INFORMATION

GENERAL INSTRUCTIONS

Please read these instructions completely before performing testing. Not doing so may give inaccurate test results.

General Test Preparations

- Place the test stand on a flat surface. Use only the stand provided.
- Using the notched corner, tear the top of the divided pouch containing the testing device and vial of developer solution.
- **To prevent contamination, leave testing device in its pouch until needed.**
- Remove the vial of developer solution.
- Firmly holding the vial, carefully uncap the vial by gently rocking the cap back and forth.
- Slide the now uncapped vial into the angled stand making sure the vial is completely seated in the stand. **DO NOT** snap the vial into the stand as splashing may occur.

Quality Control

OraQuick HIV-1 Kit Controls are supplied separately.

- Read the OraQuick HIV-1 Kit Controls Package Insert before proceeding. Not doing so may give inaccurate test results.
- The Kit Controls verify that the test is working properly. Persons administering and reading OraQuick Rapid HIV-1 Antibody Tests **MUST** run these Kit Controls whenever there is a change to a different lot number of tests.
- If the results of the control tests match the expected results, proceed with specimen testing.
- If the results of the control tests **DO NOT MATCH** the expected results, perform a repeat test with the Kit Controls using another complete OraQuick Rapid HIV-1 Antibody Test.
- If the results of the repeat test match the expected results, proceed with specimen testing. If the results of the repeat test **DO NOT MATCH** the expected results, call OraSure Technologies Customer Service for technical assistance.

Material Disposal

Dispose of all potentially contaminated materials in accordance with local regulations for disposal of infectious waste.

For answers to questions regarding the OraQuick® Rapid HIV-1 Antibody Test or for more information on other OraSure Technologies' products, call: 1-800-869-3538 or visit our web site: www.orasure.com

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Step-by-Step Instructions for OraQuick® Rapid HIV-1 Antibody Test Sample Collection & Testing Procedures

Fingerstick Blood Test

Step 1

Clean finger with an antiseptic wipe. **Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.** Use a lancet to puncture finger. Allow a drop of blood to form.

Step 2

Touch the specimen collection loop to the blood. Visually inspect the loop to make sure that it is **completely** filled with blood.

Step 3

Put the blood-filled loop into the developer solution inside the vial. Use the loop to stir the specimen in the vial of developer solution. Solution will appear pink if the blood specimen was properly introduced. Remove the disposable loop and discard as infectious waste.

Step 4

Remove the testing device from its pouch. Insert the testing device, flat pad first, into the test developer solution vial containing the specimen. Be sure that the results window faces forward and the flat pad touches the bottom of the vial.

Step 5

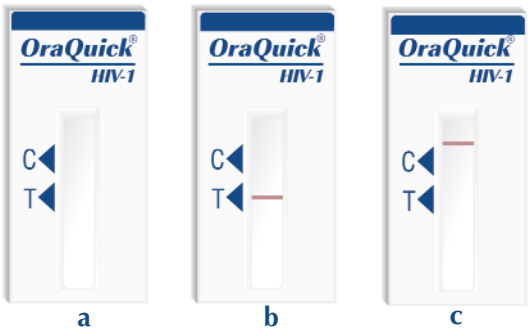
Start timing the test. Read the results after 20 minutes. Do not exceed 60 minutes.

Turn to the Reading Test Results section of these instructions. Read and record the test results.

After recording the results, dispose of used testing materials in accordance with local regulations for infectious waste.

Reading Test Results

APPROPRIATE LIGHTING REQUIRED



Reading an INVALID result:

- No line appears in the control (C) area, indicating that the test did not function properly (examples a & b).
- If line is outside of the blue triangle the test is invalid. (example c)

For an INVALID result:

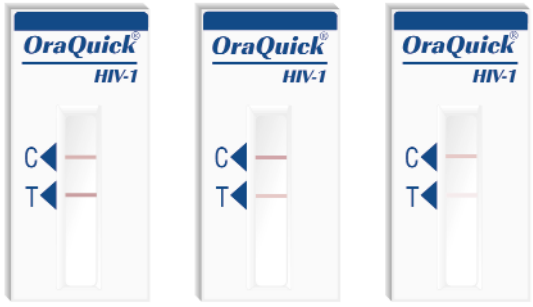
- With an oral fluid specimen, the test should be performed again with a new device using a blood specimen.
- With a blood specimen, the test should be performed again using a new device and blood sample.
- If a second test should fail, contact OraSure Technologies Customer Service Dept.

Reading a NEGATIVE result:

- Only the control (C) area shows a line.
- No line is present in the test (T) area.
- A negative test suggests an absence of HIV antibodies in the specimen.

For a NEGATIVE result:

Refer to CDC Guidelines for appropriate counseling messages



Reading a REACTIVE result:

- Lines appear in both the control (C) and test (T) areas. **Even a very faint test (T) band should be read as reactive.**
- One line may appear lighter or less consistent than the other.
- A reactive result indicates the presence of HIV antibodies in the specimen.

For a REACTIVE result:

Refer to CDC Guidelines for appropriate counseling messages

- Supplemental Test to confirm results will need to be performed

NOTE:

If at 20 minutes:

- a red background in the results window makes it difficult to read the results and/or,
- the control line is not visible, then wait to read the results up to 60 minutes total time. (*Occasionally lines at the "T" section may develop on otherwise negative devices after 60 minutes. These late-developing lines do not reflect a correct result and should be disregarded.)*